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Fish Genes into Tomatoes: How the World Regulates Genetically Modified Foods

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FISH GENES INTO TOMATOES: HOW THE WORLD REGULATES GENETICALLY MODIFIED FOODS

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I. INTRODUCTION

In making what appeared to be a normal taco salad, Grace Booth combined garlic, cheese, chicken, corn tortillas, and enchilada sauce.[1] After finishing her meal, Booth felt fine.[2] Ten minutes later, however, Booth's throat suddenly began to close, and her entire body began to itch.[3] She was rushed to a hospital where she went into shock and nearly died after eating taco shells that contained a type of corn deemed unsafe for human consumption.[4] The corn, which was genetically modified by Aventis and contained a toxin used to killed insects, had been ruled unsafe for human consumption by the Environmental Protection Agency (EPA) because of possible indigestible and allergic qualities.[5] Nevertheless, the product found its way into taco shells and on to American grocery shelves for persons, such as Booth, to enjoy as part of their favorite meal.[6]

Genetically modified foods (GM Foods), made from genetically modified organisms (GMOs), are present in over three-quarters of the products available on grocery store shelves, yet the American public remains unaware that GM Foods are present in most of the foods they consume each and every day.[7] For thousands of years, scientists and farmers have created

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1. KATHLEEN HART, EATING IN THE DARK 3 (2002).
2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.*
6. *See id.*
7. Mike Lee, *Confusion, Ignorance About Biotech Food*, SACRAMENTO BEE, Sept. 18, 2003, *at* http://www.organicconsumers.org/ge/ge_regulation.cfm (last visited Oct. 8, 2004) (noting that while 75% of processed foods contain genetically engineered ingredients, only 24% of Americans surveyed believed that they had eaten GM Foods). *See also* HART, *supra* note 1, at 6 (noting that as of 1999, only 6% of American consumers knew the food they were eating contained genetically modified corn, and only 3% of Americans knew they were eating genetically modified soybeans); Elizabeth Weise, *Americans are Iffy on Genetically Modified Foods*, USA TODAY, Sept. 17, 2003, at 6D, *available at* http://www.organicconsumers.org/ge/ge_regulation.cfm (noting that "the

more desirable species of plants and animals by using selective breeding.[8] The poodle dog and the long-stem red rose both were transformed through selective breeding, as nature combined selective genes together to form a new species.[9] Genetic engineering is similar in some ways, but different in others. "Genetic engineering allows scientists to speed the [transformation] process up by moving desired genes from one plant to another—or even from an animal to a plant or vice versa."[10]

The United States has taken the stance that GM Foods are in no way different than conventional foods.[11] However, various international organizations, including the United Nations (UN) and the European Union (EU), have taken a much tougher position on food biotechnology.[12] This paper will analyze the differing regulatory standpoints of the United States and international organizations and foreshadow possible effects of these regulations. Part II of this paper discusses food biotechnology and GM Foods in general. Part III of this paper analyzes the regulatory system in place in the United States. Part IV of this paper looks at the ways in which the UN and the EU regulate GM Foods. Part V of this paper foreshadows possible future benefits and problems from the current international regulation of GM Foods. Part VI concludes this paper.

II. WHAT ARE GENETICALLY MODIFIED FOODS?

As there are many different food products that are genetically modified, there are also many different definitions for "food biotechnology." In Canada's Volume I of the *Guidelines for the Safety Assessment of Novel Foods*, biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms."[13] The Cartagena

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Grocery Manufactures of America says 70% to 80% of processed foods sold in supermarkets contain products made from genetically engineered corn, soybeans or cottonseed oil").

8. Yahoo! Health, *Genetically Engineered Foods* (June 5, 2002), *at* http://health.yahoo.com/health/ency/002432/-overview.

9. *Id.*

10. *Id.*

11. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984 n.3 (May 29, 1992) (stating "[m]ost, if not all, cultivated food crops have been genetically modified"); Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 720 (2000).

12. *See generally* Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 37 TEX. INT'L L.J. 173 (2000).

13. Pearl Reimer & Bryan Schwartz, *Trade & Genetically Modified Foods: Biotechnology: A Canadian Perspective*, 1 ASPER REV. INT'L BUS. & TRADE L. 91, 91 (2001) (quoting HEALTH CANADA: FOOD DIRECTORATE, GUIDELINES FOR THE SAFETY ASSESSMENT OF NOVEL FOODS, vol. I, annex I , at 6 (1994)). Although there may be some technical difference between the two,

Protocol on Biosafety defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify the products or processes for a specific use."[14] On a more political level, however, "the term [biotechnology] is generally used to refer to newer biotechnology techniques, particularly the use of recombinant DNA (rDNA) techniques to modify organisms at the genetic level."[15]

Although there are many ways to define it, biotechnology has historically been used to modify the way we plant and grow crops. For example,

> Biotechnology, in the form of traditional fermentation techniques, has been used for decades to make bread, cheese or beer. It has also been the basis of traditional animal and plant breeding techniques, such as hybridization and the selection of plants and animals with specific characteristics to create, for example, crops which produce higher yields of grain.[16]

Today, however, biotechnology has become more detailed and sophisticated, as "researchers can now take a single gene from a plant or animal cell and insert it in another plant or animal cell to give it a desired characteristic, such as a plant that is resistant to a specific pest or disease."[17] One example of biotechnology is the use of B.t. genes in crops. B.t., which stands for *Bacillus thuringiensis*, "is a naturally occurring bacterium that produces crystal proteins that are lethal to insect larvae. B.t. crystal protein genes have been transferred into corn, enabling the corn to produce its own pesticides against insects such as the European corn borer."[18]

Scientists have used biotechnology to create a host of other plant species over the past few decades. These include transferring fish genes into potato plants so plants can withstand cold temperatures, modifying canola plants so the plants can grow in under-developed soils, and creating rice varieties that are more tolerant to dry, drought-like conditions.[19] While

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for purposes of this paper, the author uses the terms "genetically modified" and "genetically engineered" to be the same term.

14. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Frequently Asked Questions on the Biosafety Protocol*, *at* http://www.biodiv.org/biosafety/faqs.asp?area=biotechnology&faq=1 (last modified Aug. 23, 2004).

15. Adler, *supra* note 12, at 175.

16. Secretariat of the Convention on Biological Diversity, *supra* note 14.

17. *Id.*

18. Deborah B. Whitman, *Genetically Modified Foods: Harmful or Helpful?*, CAMBRIDGE SCI. ABSTRACTS, Apr. 2000, *at* http://www.csa.com/hottopics/gmfood/oview.html.

19. Reimer & Schwartz, *supra* note 13, at 92-93; Whitman, *supra* note 18; Stephen Kelly Lewis, *"Attack of the Killer Tomatoes?" Corporate Liability for the International Propogation of Genetically Altered Agricultural Products*, 10 TRANSNAT'L LAW. 153 (1997).

on their face these examples seem to present nothing but a bright future for GM crops, it is important to analyze both the potential benefits and harm from growing, harvesting, and eating these plants.

There are many advantages to using biotechnology in the world's agricultural systems. First, crops can be changed to resist or tolerate certain pests, climates, and drought.[20] These features, when added to crops, can reduce the amount of chemical pesticides placed in our environment, improve the chances of crops surviving harsh weather, and prevent certain plant diseases.[21] Second, crops can be genetically modified to increase the plant's nutritional value. This change could be extremely beneficial to third-world nations, where malnutrition is commonplace.[22] As Deborah Whitman points out,

> Malnutrition is common in third world countries where impoverished peoples rely on a single crop such as rice for the main staple of their diet. However, rice does not contain adequate amounts of all necessary nutrients to prevent malnutrition. If rice could be genetically engineered to contain additional vitamins and minerals, nutrient deficiencies could be alleviated. For example, blindness due to vitamin A deficiency is a common problem in third world countries.[23]

Besides adding vitamins and minerals to rice, there are other techniques used by scientists to increase the nutritional value of foods. These include increasing the amount of unsaturated fat content in canola, soybean, and corn and altering the genetic makeup of potatoes to the point where they absorb less oil when they are actually cooked.[24] Third, food biotechnology is used for medicinal purposes. Scientists are working on using biotechnology to store and ship edible forms of vaccines inside of tomatoes and potatoes.[25] By shipping them in an edible form, scientists are working to increase the likelihood that persons in third world countries can utilize the vaccines.[26] In addition, "[r]esearch is also underway to develop plants that produce antibodies to fight measles, tooth decay and sexually transmitted diseases."[27]

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20. Reimer & Schwartz, *supra* note 13, at 92-93; Whitman, *supra* note 18 (noting that GM foods can be created to resist pests and disease and to tolerate herbicides and cold).

21. Whitman, *supra* note 18.

22. *See id.*

23. *Id.*

24. Reimer & Schwartz, *supra* note 13, at 93.

25. Whitman, *supra* note 18.

26. *See id.*

27. Reimer & Schwartz, *supra* note 13, at 93.

In the end, "[g]enetic engineering may provide a means of developing less costly varieties of crops and increasing the ability of crops to resist major diseases."[28] Nevertheless, while significant benefits can clearly be seen from growing and harvesting these crops, the hazards and potential risks to the general public are less than certain.[29] First, environmental activists note that there could be unintended harm to other organisms by growing GM Foods.[30] One study suggests that organisms could be harmed or even become extinct due to GM Foods and their effect on the food chain; however, there is no definitive answer on the harm GM Foods present to society.[31] Currently, the U.S. Department of Agriculture (USDA), the EPA, and numerous other groups are currently studying the possible effect of GM Foods on organisms.[32] Second, some scientists fear that by making crops resistant to pesticides, cross pollination and cross breeding may cause other plants to become resistant to pesticides as well, resulting in a breed of "superweeds."[33] Several commentators have presented possible solutions to this "superweed" dilemma, including creating buffer zones around GM crops and creating only sterile GM crops, but no one method has been confirmed as the most beneficial answer to this problem.[34] Third, some critics note that by combining genes together and creating new species, new allergens could be formed that could be detrimental to society.[35] Because millions of people around the globe are already allergic to some foods and food ingredients, it is clear how the addition of new allergens into the food chain could be potentially damaging. Fourth, one commentator specifically notes that "genetic modification may also cause some economic concerns."[36] Some farms may not be able to handle the cost of producing the crops and thus may find themselves at a disadvantage, and some countries that have neither the financial nor technological means to produce GM

28. Michele J. Brace, Comment, *Regulation of Genetically Engineered Foods Under the Federal Food, Drug, and Cosmetic Act*, 33 AM. U. L. REV. 899, 900-01 (1984).

29. *Id.* at 901.

30. Whitman, *supra* note 18.

31. Martin Teitel & Kimberly Wilson, *What the Future Holds*, *available at* http://www.abetterearth.org/subcategory.php/195.html (last visited Jan. 13, 2005) (excerpted from GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE (2001)) (noting "[w]ho knows which natural species might be driven toward extinction by competition with escaped genetically modified organisms").

32. *Id.*

33. *Id.*; Reimer & Schwartz, *supra* note 13, at 97.

34. *See* Whitman, *supra* note 18.

35. *Id.*; *see also* Reimer & Schwartz, *supra* note 13, at 96.

36. Reimer & Schwartz, *supra* note 13, at 97.

Foods may find themselves losing a battle with larger, more sophisticated nations that are able to export and import GM crops.[37]

It is because of these potential risks and disadvantages that nations around the globe handle and regulate GM Foods differently. The United States has spent the last few years attempting to convince other nations to give more lenient treatment to these foods; however, it has been a slow and steady mission for the United States government.[38]

III. THE UNITED STATES REGULATION OF GM FOODS

A. THE FOOD AND DRUG ADMINISTRATION'S ROLE

The FDA has the authority to regulate all foods grown, produced, and otherwise manufactured in the United States via Congress's enactment of the Federal Food, Drug, and Cosmetic Act (the Act).[39] When handling the regulation of food products, the FDA works with the USDA and the EPA.[40] Nevertheless, the United States judicial system has interpreted the Act to give broad discretion to the FDA to make all rules necessary governing food products in order to promote the public's interest.[41] More specifically, the Act prohibits,

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded; (b) [t]he adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce; (c) [t]he receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise . . . [and] (g) [t]he

37. *Id.*; *see also* Whitman, *supra* note 18 (noting concerns of consumer advocates that "patenting these new [GM] plant varieties will raise the price of seeds so high that small farmers and third world countries will not be able to afford seeds for GM crops, thus widening the gap between the wealthy and the poor").

38. *See infra*, notes 88, 121, 122, and 130, and accompanying text.

39. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 341 (2003) (stating that "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food"); Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992); Sheldon Krimsky & Nora K. Murphy, *Epidemiology and Science: Biotechnology at the Dinner Table: FDA's Oversight of Transgenic Food*, 584 ANNALS 80, 82 (2002).

40. *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22984 (noting that the USDA "regulates meat and poultry products" while the EPA "regulates pesticides and sets tolerances for pesticide residues in foods").

41. *See* Brace, *supra* note 28, at 903 n.22 (offering federal case law construing the Act).

> manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.[42]

Therefore, it will be necessary (1) to look at how the Act defines "food" and how the Act defines foods that are "adulterated" and (2) to look at the procedures for handling the regulation of GM Foods that are somehow misbranded or mislabeled.

"Food," under the Act, is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[43] Because the Act contains such a broad and general definition of food, genetically modified foods are included within the Act's definition of food and can be regulated under the Act's provisions.[44] Therefore, if a genetically modified food is adulterated, it should be regulated under the Act. A food is adulterated if the food "bears or contains any poisonous or deleterious substance which may render it injurious to health . . . [or if] any valuable constituent has been in whole or in part omitted or abstracted therefrom [or] if damage or inferiority has been concealed in any manner."[45] The FDA can regulate adulterated foods "because of the presence of a toxicant, which is a poisonous or deleterious substance."[46] The FDA has two different means of regulating toxicants in food. First, "[t]he FDA may seize a food that naturally contains a toxic substance if the government can show that the quantity of the endogenous toxicant would 'ordinarily render' the food injurious to health."[47] Second, "the FDA has authority to seize any food that contains an added toxicant if the government can show that the added substance 'may render' the food injurious to health."[48]

Therefore, so long as GM Foods are not adulterated and do not naturally or otherwise contain a toxicant, the United States government has deemed it acceptable to treat the foods the same as all non-GM Foods that are not adulterated. In other words, if the foods are not adulterated, the United States government takes the position that GM Foods should not be regulated. As such, it remains important to review the regulatory policies of the FDA.

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42. 21 U.S.C. § 331(a)-(c), (g) (2003).
43. *Id.* § 321(f).
44. *See* Brace, *supra* note 28, at 903 n.23.
45. 21 U.S.C. § 342(a)(1), (b)(1), (b)(3) (2003).
46. Brace, *supra* note 28, at 904.
47. *Id.* at 904 n.32 (citing 21 U.S.C. § 342(a)(1) (1982)).
48. *Id.* (citing 21 U.S.C. § 342(a)(1) (1982)).

B. THE FDA POLICY STATEMENTS & CONSULTATION

President George W. Bush has noted that,

> Genetic engineering will enable farmers to modify crops so that they will grow on land that was previously considered infertile . . . [and] will enable farmers to grow produce with enhanced nutritional value. Our nation stands as a global leader in research and development, in large part because of our successes in understanding and utilizing the biological processes of life.[49]

The FDA has taken a similar position on GM Foods. In 1992, the FDA issued a policy document stating that transferring genetic materials into crops is generally regarded as safe.[50] With this policy statement, the FDA thus determined (1) that GM Foods do not contain naturally occurring toxins and (2) that the process of food biotechnology does not "add" additional toxins into other foods.[51]

While the "FDA recommended that food producers consult with [the Agency] before marketing rDNA-produced foods,"[52] the Agency still guaranteed itself the final say in any GM Food product, because the "FDA reserved the right to regulate any particular rDNA-developed food that [the] FDA believed was unsafe on a case-by-case basis, just as [the] FDA would regulate unsafe foods produced through conventional means."[53] The FDA reasoned that it simply did "not have the time, money, or resources to carry out exhaustive health and safety studies of every proposed GM food product."[54] As such, the FDA did not develop any specific consultation or testing procedures for those who grow, test, and sell GM Foods.[55] Instead, a voluntary consultation was placed into effect, and this voluntary consultation process remains in effect today.[56]

The initial consultation procedures were established in 1992 and amended in 1994, 1996, and 1997.[57] As of 1997, "[n]o specific time frame

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49. HART, *supra* note 1, at 277.

50. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992); HART, *supra* note 1, at 6-7 (noting that the FDA, after studying scientific research and knowledge available in the 1990's when GM foods first hit the market, has taken the position that GM foods are safe); Whitman, *supra* note 18.

51. *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22984.

52. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.C. 2000).

53. *Id.*

54. Whitman, *supra* note 18.

55. *See id.*

56. *Id.*

57. Krimsky & Murphy, *supra* note 39, at 83.

[was] set for the FDA to complete its consultation with a developer."[58] In fact, "[a]s of April 2000, the median time for the FDA to complete its consultation review was *155 days*, and the average time was *175 days*."[59] Nevertheless, the FDA stated that "it is in the best interests of the regulated industry and the agency for developers to inform [the] FDA . . . prior to commercial distribution, about foods or feed derived from new plant varieties, including those derived using rDNA techniques."[60] As such, in 2001,

> the FDA issued a proposed rule that would require that developers submit a scientific and regulatory assessment of the bioengineered food 120 days before the bioengineered food is marketed. In the premarket notification proposal, [the] FDA recommends that developers continue the practice of consulting with the agency before submitting the required premarket notice.[61]

After the comment period ended, this proposed rule became a requirement.[62]

While the FDA still does not require that GM Foods be subjected to a mandatory consultation process, it may be leaning towards applying more regulatory requirements on GM Food manufacturers and distributors. Nevertheless, because of the time and profit delays it causes a company, it remains to be seen how many companies will take part in the current consultation process, once they have completed their required scientific and regulatory assessment.

C. MANDATORY LABELING

Numerous consumer groups and organizations and even some United States Congressional members are pushing for a national labeling law for GM Foods.[63] Some citizens in Oregon went a step further and collected

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58. *Id.*

59. *Id.* (emphasis added).

60. FDA, *Guidance on Consultation Procedures: Foods Derived From New Plant Varieties* (Oct. 1997), *at* http://www.cfsan.fda.gov/~lrd/consulpr.html.

61. FDA, *List of Completed Consultations on Bioengineered Foods* (Oct. 2002), at http://www.cfsan.fda.gov/~lrd/biocon.html; Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001) (codified at 21 C.F.R. §§ 192, 592 (2003)).

62. 21 C.F.R. §§ 192, 592 (2003).

63. HART, *supra* note 1, at 269-70 (noting that 500,000 Americans wrote the FDA in 1999 and urged the governmental agency to impose a mandatory labeling requirement for GM foods); Congressman Dennis J. Kucinich, *Agriculture*, *at* http://www.house.gov/kucinich/issues/agriculture.htm (last visited Oct. 22, 2003); *see generally* The Campaign to Label Genetically Engineered Foods, *at* http://www.thecampaign.org/index.php (last visited Oct. 22, 2003); The Alliance for Bio-Integrity, *at* http://www.bio-integrity.org/ (last visited Oct. 22, 2003); The Center For Food Safety, *at* http://www.centerforfoodsafety.org/home.cfm (last visited Oct. 22, 2003).

enough signatures to put a labeling requirement measure on the November 2002 general election ballot.[64] Overall, the FDA has received intense pressure to require labeling of GM Foods.[65] On the other hand, the Grocery Manufacturers of America took the position that labeling genetically modified foods "would imply that [the foods] are less safe or less wholesome than their traditional counterparts."[66] One commentator specifically argues that labeling GM foods with a "common label" would confuse consumers.[67]

Whether or not to impose a labeling rule on GM Foods raised many questions that the FDA had to analyze. First, the FDA had to ask if consumers were willing to absorb the cost of a labeling law, as food companies would have to increase costs to adjust for decreased sales and increased testing, manufacturing, farming, and labeling costs.[68] Second, the FDA would have to determine what would be considered a necessary amount of genetically modified product in a final food product to require the label.[69] Would one percent be an acceptable limit, or on the other hand, would the FDA require labeling on foods containing an even smaller percentage of total GMOs? Third, and possibly most important, who would be held responsible for educating the public on how to read the new labels and about the basics of GM Foods?[70] Because only a small percentage of the population is knowledgeable of GM Foods,[71] it would take considerable time and money to teach the public enough about GM Foods to make the population comfortable with any new labeling requirements.

The Act does grant authority to the FDA to establish labeling requirements for all food products.[72] As one commentator states, the "FDA has an interest in ensuring that any voluntary [or mandatory] labeling

64. *See generally* Vote Yes on Measure 27!, *at* http://www.voteyeson27.com (last visited Oct. 22, 2003). The Oregon measure was defeated at the polls, and there is currently no plan to bring the measure back to the Oregon ballot in future elections. *Id.*

65. Goldman, *supra* note 11, at 720; Alicia T. Simpson, Note, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?*, 19 TEMP. ENVTL. L. & TECH. J. 225, 226 (2001).

66. HART, *supra* note 1, at 37.

67. Alan McHughen, *Predicted Failure of Mandatory Labels for Genetically Modified Foods*, University of Saskatchewan SCOPE GM Food Controversy Forum, Jan. 20, 2001, *available at* http://www.biotech-info.net/predicted_failure.html (stating "A common label fails to distinguish real potential hazards. Putting the same label on every GM food, even if it is feasible, will be misleading and confusing to consumers.").

68. *See* Whitman, *supra* note 18.

69. *Id.*

70. *Id.*

71. *See supra* note 7 and accompany text.

72. 21 U.S.C. § 343 (2003).

program is truthful and not false or misleading."[73] The FDA is entitled to enforce labeling requirements on a food if the end food product,

> fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.[74]

However, when confronted with the question of whether or not to label GM Foods, "the Federal Government has deemed it unnecessary to establish national labeling standards."[75] The FDA ultimately concluded that GM Foods are not materially different than their non-GM Food counterparts, and therefore, labeling would not be required for GM Food.[76] In the end, the FDA has determined that "for the most part, information concerning the biotechnology-derived status of a food or food ingredient is not material. This view reflects the agency's scientific judgment as to the safety of the technology and the lack of materiality in difference between a modified food and its traditional counterpart."[77]

Nevertheless, in true governmental form, the FDA imposed four exceptions to when GM Foods would be required to be labeled as such on food products.[78] First, when a food is significantly different from a non-GM counterpart and "the common or usual name no longer adequately describes the new food,"[79] then "the FDA would require the producers to change the name to one that illustrates the variation."[80] "The second exception applies when an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, and then a statement must be made on the label to describe the issue."[81] Third, "when a bioengineered food has significantly different nutritional propert[ies], . . .

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73. Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD DRUG L.J. 301, 310 (2000).

74. 21 U.S.C. § 321(n) (2003).

75. Andre J. Nicholas, *As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified Foods*, 15 LOY. CONSUMER L. REV. 277, 289 (2003).

76. Degnan, *supra* note 73, at 309.

77. *Id.*

78. Emily Robertson, Note, *Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 160 (2003).

79. *Id.*

80. *Id.*

81. *Id.*

then its label must reflect the difference."[82] Finally, "if a new food includes an allergen that consumers would not expect to be present based on the name of the food, . . . then the presence of that allergen must be disclosed on the label."[83] In the end, if one of these four narrow exceptions does not apply, the FDA does not require that any special labeling requirements be imposed on GM Foods; therefore, GM Food manufacturers generally must only resort to labeling their products in the same manner as all other food products.[84] The FDA shows no signs of reversing its current position.

IV. INTERNATIONAL REGULATION OF GENETICALLY MODIFIED FOODS

"[N]ational and international tribunals are offering new, and much more effective, means for enforcing international law."[85] Therefore, while the United States may be an international superpower and be respected from country to country around the globe, it is the means in which other nations regulate GM Foods that will ultimately determine the extent to which GM Foods are accepted around the globe. The United States will have difficulties exporting their GM Foods and selling their food products to Europe, Asia, and Africa if the governments that make up these continents do not openly embrace the new food biotechnology. Thus, this article will examine two key worldwide organizations, the EU and UN, how they handle the regulation of GM Foods, and attempt to predict the future of GM Food regulation.

A. THE EUROPEAN UNION

As of 2000, compared to 51.25 million acres of land in the United States, GM crops were planted and harvested in only 500,000 acres of land in Europe.[86] Thus, it might be expected that the EU has been much more strict on the importation and regulation of GM Foods in their member states. Six European countries had a moratorium on the cultivation of GM Foods in place in July 2003.[87] Moreover, "[a] five-year suspension by the EU on GM crops, which end[ed in 2003,] has caused friction between the EU and the United States, where GM technology has been pioneered and

82. *Id.*

83. *Id.*

84. *See id.*

85. BARRY E. CARTER ET AL., INTERNATIONAL LAW 15 (4th ed. 2003).

86. J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD DRUG L.J. 105, 106-07 (2000).

87. Global News Wire, *More on New EU Labeling Law on GE Food & Crops* (July 23, 2003), *at* http://www.organicconsumers.org/ge/eu_ge_labeling_law.cfm.

has been commercially successful."[88] As the five-year suspension ended, the EU decided to pass new legislation to handle the regulation of GM Foods.[89]

The Commission of European Communities met in July 2003 to develop new guidelines for its member states to follow when dealing with GM Foods.[90] Under the proposed rules, which became EU regulation in 2003, the Commission developed two new requirements for dealing with GM Foods: (1) a traceability requirement and (2) a labeling requirement.[91] In regards to the traceability requirement, the Commission decided that,

> the new Regulation on traceability . . . will require business operators when using or handling GM products to transmit and retain information at each stage of the placing on the market. Information concerning the presence of GMOs in products must be transmitted throughout the commercial chain and must be retained for five years.[92]

Overall, "[t]raceability provides the means to track the movement of genetically modified products through the production and distribution chains."[93] Or, more specifically, governments can be more prepared to handle liability issues. This change in policy could improve relations with the United States, since in 1999 the "[i]mport[ation] of corn and soybean[s] from the [United States] was also hampered because the [United States] could not distinguish shipments containing genetically modified crops."[94] In regards to the labeling requirement, the Commission decided that,

> [t]he new law will extend the current labeling requirements to also cover [GM Foods] and food ingredients produced from GMOs . . . and to allow consumers to exercise their freedom of choice. The label has to indicate "This product contains genetically modified

88. Mona Mcalinden, *Backing for Europe over GM*, SUNDAY HERALD (Scotland), Sept. 21, 2003, at 4.

89. *See* Opinion of the Commission, EUR. PARL. DOC. (COD/2001/0180) (July 18, 2003), *available at* http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.ProcedureView?lang=2&procid=1895\.

90. *Id.*

91. Final Decision, EUR. PARL. DOC. (COD/2001/0180) (Sept. 22, 2003), *available at* http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.ProcedureView?lang=2&procid=1895\.

92. *Id.*

93. *See* Opinion of the Commission, EUR. PARL. DOC. (COD/2001/0180) (July 18, 2003), *available at* http://wwwdb.europarl.eu.int/oeil/oeil_viewdnl.ProcedureView?lang=2&procid=1895.

94. Kim Brooks, *History, Change and Policy: Factors Leading to Current Opposition to Food Biotechnology*, 5 GEO. PUB. POL'Y. REV. 153, 154 (2000).

organisms" or ". . . produced from genetically modified (name of organism)."[95]

"The EU food industry [had] six months to get to grips with the legislation, under which all products containing more than 0.9 percent of genetically modified organisms [had] to be labelled [sic]."[96] The actual wording on the label is important, as it will allow European Union citizens to know which of the products on their grocery shelves contain GMOs without confusion.

Overall, the EU's proposed guidelines allow for the co-existence of GM Foods with non-GM Foods and organic foods. "In guaranteeing the co-existence of genetically-engineered and ordinary crops, the European Commission believes the most efficient and cost-effective practice ultimately comes down to national and regional or local conditions."[97] Because of this reason, the EU gives its member states a great deal of leeway in deciding how to regulate GM Foods.[98] For example, member states can use on-farm measures, such as isolation distances between crops, co-operation between neighboring farms, monitoring schemes, notification schemes, training for farms, and advisory services when deciding ways to regulate GM Foods.[99]

Whether or not the EU regulations are well received by the member states and further the EU Commission's goal of promoting the co-existence of GM and non-GM Foods will not be seen for many years. Nevertheless, current regulations still show the willingness of the EU to compromise with the United States and allow GM crops to enter the nation's commerce stream.

B. THE CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on Biosafety (the Protocol), enacted through the Convention on Biological Diversity and the United Nations, is a convention signed between nations across the globe to regulate, among other

95. Final Decision, EUR. PARL. DOC. (COD/2001/0180) (Sept. 22, 2003), *available at* http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.ProcedureView?lang=2&procid=1895\.

96. Reuters, *EU Finalizes Strict Labeling Law for GMOs*, July 22, 2003, *at* http://www.organicconsumers.org/ge/eu_gmos_labels.cfm (last visited Dec. 31, 2004).

97. *Biotechnology: Recommendations on Co-Existence of GM and Non-GM Crops*, EUROPEAN REP., July 26, 2003, *available at* 2003 WL 57539131.

98. *See id.*

99. Press Release 46/03, European Union, Delegation of the European Commission to the United States, GMOs: *Commission Publishes Recommendations to Ensure Co-Existence of GM and Non-GM Crops* (July 23, 2003).

areas, GM Foods.[100] The Protocol was adopted on January 29, 2000.[101] The Convention has many objectives, including "the conservation of biological diversity, the sustainable use of its components and equitable sharing of the benefits arising out of the utilization of genetic resources."[102] When drafting the Protocol, the contracting nations addressed the transfer and handling of the products and on the conservation and sustainable use of biological diversity.[103] Most importantly, under the Protocol, "countries will have a right under international law to ban imports of food containing genetically modified organisms (GMOs) that they think could be unsafe."[104] The Protocol was enacted because although "advances in biotechnology have great potential for significant improvements in human well-being, [the foods] must be developed . . . with adequate safety measures for the environment and human health."[105]

On October 11, 2003, the UN's Biosafety Protocol became law for all nations who signed the convention.[106] Although the United States is not bound by the Protocol, the United Nations has great influence on other nations around the world. For example, the Protocol has been adopted by more than 130 countries to date.[107] Therefore, it is important to analyze the framework of the Protocol and use the Protocol to foreshadow the future regulation of GM Foods.

The Protocol focuses specifically on foods containing any and all living modified organisms that could pose risks to human health.[108] As part of the Protocol, countries are given the right to assess the risks associated with GM Food products.[109] The Protocol "ensure[s] that countries are provided with the information necessary to make informed decisions before agreeing

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100. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: About the Protocol*, *at* http://www.biodiv.org/biosafety/background.asp (last updated Aug. 28, 2002) [hereinafter *Cartagena Background*].

101. *Id.*

102. Secretariat of the Convention on Biological Diversity, *supra* note 14.

103. *Id.*

104. Fred Pearce, *GMO Import Ban Caught in Crossfire*, NewScientist.com News Service, Sept. 10, 2003, at http://www.newscientist.com/article.ns?id=dn4147.

105. Secretariat of the Convention on Biological Diversity, *supra* note 14.

106. NewScientist.com News Service, *Global GE Import Regulations Stir up Controversy*, Oct. 10, 2003, *at* http://www.organicconsumers.org/ge/ge_imports.cfm (last visited Oct. 11, 2003).

107. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Ratification of the Cartagena Protocol on Biosafety and its Entry into Force*, *at* http://www.biodiv.org/biosafety/ratification.asp (last modified Nov. 12, 2003). The first meeting of the member states was planned for February 23-27, 2004, in Kuala Lumpur, Malaysia. *Id.*

108. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Text of the Protocol, art. 4*, *at* http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-04 (last modified May 27, 2004).

109. *Cartagena Background*, *supra* note 100.

to the import of such organisms into their territory."[110] The Protocol reaches this goal by requiring that a member country notify another member country if any exported goods contain living modified organisms.[111] The Protocol makes sure to note that "[r]isk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner . . . in order to evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health."[112] Thus, under the Protocol, a nation cannot prevent the importation of a living modified organism (LMO) from another member country unless there is sound scientific evidence to show there will be some adverse effect on the people of the importing country. With this in mind, the Protocol is more GM-friendly than one may think at first glance as this convention merely provides for the uninhibited transfer of information from one member country to the next.

As a matter of fact, the Biosafety Clearing-House (BCH) requires all member countries to disclose information for viewing by all other member countries including national biosafety laws, risk assessment summaries, and the final decision by importing parties (along with their supporting reasons).[113] The BCH must be notified of all final decisions within 270 days of the matter first being proposed to another member country.[114] Violators of the Protocol face a stiff monetary penalty: "[i]f an illegal shipment of LMOs occurs, the affected Party may request the Party of origin of the shipment to repatriate or destroy the LMO at its own expense."[115] Overall, it appears that the Protocol is, in fact, more concerned with open communication between member nations than it is concerned with the handling of GM Foods. Nevertheless, with open communication, member states may be more willing to accept food biotechnology.

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110. *Id.*

111. Article 18 of the Protocol focuses on the labeling of these goods. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Text of the Protocol, art. 18, at* http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-18 (last modified May 27, 2004); *see also* Secretariat of the Convention on Biological Diversity, *supra* note 107.

112. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Text of the Protocol, art. 15, at* http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-15 (last modified May 27, 2004).

113. Secretariat of the Convention on Biological Diversity, *supra* note 107; Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Text of the Protocol, art. 10, at* http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-10 (last modified May 27, 2004); Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Text of the Protocol, art. 11, at* http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-11 (last modified May 27, 2004).

114. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety: Text of the Protocol, art. 11, supra* note 113.

115. Secretariat of the Convention on Biological Diversity, *supra* note 107.

V. FORESHADOWING THE FUTURE OF GM FOOD REGULATION

The world is not one-hundred percent ready for the free-for-all introduction of genetically modified foods into the marketplace, since in the last few years, for example, there have been demonstrations around the world. As one author noted,

> In England, for example, activists are known to break into government-sponsored test sites to destroy genetically modified crops in an effort to "decontaminate" the fields. In the United States—the world's largest producer of genetically engineered products, concern is also mounting. Last year the [United States] Congress received petitions with half a million signatures requesting that genetically modified products be labelled [sic]. Canadians are also becoming increasingly concerned. According to a recent Angus Reid survey, 67% of Canadians would be less likely to purchase a food product if they knew it had been genetically engineered.[116]

In fact, British royalty has even called for GM Foods to be banned.[117] Speaking in July 2003 after the EU Commission developed their proposed guidelines for the handling of GM Foods, Prince Charles stated "We need a GM-free Wales—and a GM-free Britain, for that matter."[118] Such a ban would not be an unwelcome site to the people of the EU: "94.6 percent of EU citizens surveyed want the right to choose whether or not to eat foods derived from biotechnology, 85.9 percent want to know more before eating foods containing genetically modified ingredients, and 70.9 percent do not want GM food at all."[119]

Although many people around the globe disfavor the growth and consumption of GM Foods, it will be up to national governments and coalitions of national governments to determine the future regulation of GM Foods. Based on current trends and the influence of the United States of America, this author submits that more and more nations will allow the growth and sale of GM Foods within their borders, although these same nations may require certain minimum steps be taken for the goods to be sold. For example, United Kingdom Environmental Secretary Margaret Beckett recently noted that "no form of agriculture (conventional, organic, or GM)

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116. Reimer & Schwartz, *supra* note 13, at 94-95.

117. Steve Dube, *Prince Charles Calls for a GE Free Britain*, WESTERN MAIL, JULY 30, 2003 *at* http://www.organicconsumers.org/ge/ge_free_britain.cfm (last visited Sept. 30, 2003).

118. *Id.*

119. Global News Wire, *supra* note 87; Robert Uhlig, *A Wary Public Says No to GM Crops*, DAILY TELEGRAPH (London), Sept. 25, 2003, at 01.

should be excluded from the EU."[120] United Kingdom Trade and Industry Secretary Patricia Hewitt also points out a key factor that many nations must consider when developing their own rules and regulations for GM Foods: "We must also bear in mind the potential impact (on) EU-US relations."[121] These EU-US and worldwide-US relations could continue to damper United States assistance in other areas, as the GM Food resistance by other nations harms the United States economy. One estimate is that the EU's anti-GM stance alone costs United States' farmers $300 million per year.[122]

The World Trade Organization (WTO) may also play a key role in the future regulation of GM Foods. "Under the World Trade Organization regime, a threat to human health or the environment is the only basis on which a country can refuse to admit a [food] product [into its borders]."[123] Therefore, because some nations may be refusing to import GM Foods because of social reasons only, "[t]he World Trade Organization is threatening legal action against the European Union over its refusal to allow imports of unlabelled GM produce from America."[124] If the WTO is able to place enough pressure on countries, some labeling requirements could be minimized. Additional labeling issues could present problems. In January 2000, more than 130 countries, including the United States, entered into an international trade agreement, which states that exporters must label foods containing GMO's.[125] Nevertheless, this treaty could become irrelevant if some major exporters decide the labeling or non-labeling of GM Foods is affecting their overall economies or import/export statistics. The problem does not stop with a required labeling law; voluntary labeling could also lead to problems around the world. As one commentator noted, "[g]overnments can, and should, worry about whether voluntary label claims that a product is 'GMO free' are accurate. As with other voluntary claims, regulatory policies should seek to ensure that consumers get what they think they bargained for."[126]

The various solutions proposed by the EU and UN may, however, be too little, too late. "High-profile research GM companies such as Monsanto, Bayer and Dow have all closed down research facilities in Britain in recent years, drastically diminishing the career prospects of scientists

120. Mcalinden, *supra* note 88, at 4.
121. *Id.*
122. Reuters, *supra* note 96.
123. Steve Rayner, *Why Can't We Agree*, NEWSWEEK, Sept. 15, 2003, at 45.
124. Dube, *supra* note 117.
125. Whitman, *supra* note 18.
126. Beales, *supra* note 86, at 117.

working on GM crops."[127] As such, the world's biotech firms may have given up on the EU. In the end, no worldwide convention or set of regulations can repair the lack of trust the world's largest companies have in a particular region.

VI. CONCLUSION

Governments around the world are trying to do what they feel is best for their citizens. The United States government understands how important the development, sale, and exportation of GM Foods are to the United States' economy and farmers. The United States is upset with the recent decisions by the EU and UN to regulate GM Foods. For example, the United States feels that the "[EU] rules would be impossible to meet."[128] European governments, on the other hand, are particularly concerned with their citizens and how safe their citizens feel with GM Foods. For example, "the European Commission published guidelines for the development of strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic crops."[129] Robert Uhlig, writing for *The Daily Telegraph* in London, also noted the struggles that the British government faces, as "the Government [is] caught between supporting the public, who overwhelmingly do not want GM foods, and appeasing [the United States of] America, which wants to export GM crops, food and technology to Europe."[130]

Although earlier this year some African nations refused United States GM Food supplies, President Yoweri Musevini of Uganda has decided to allow GM Foods into his nation.[131] An institute has been founded in the nation to explore GM Food possibilities even though many of the country's citizens are at odds with the President's decision.[132] In addition, Kenya has also begun steps to accept GM Food technology into their nation.[133] "Already there have been several notable successes in Kenya where more than 200,000 farmers across the country have more than doubled their maize yields and substantially improved vegetable production through the

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127. John Vidal & Ian Sample, *5 to 1 Against GM Crops in Biggest Ever Public Survey*, GUARDIAN, Sept. 25, 2003, at 3, *available at* http://www.thecampaign.org/News/sept03h.php#5 (last visited Sept. 30, 2003).

128. NewScientist.com News Service, *supra* note 106.

129. Global News Wire, *supra* note 87.

130. Uhlig, *supra* note 119, at 01.

131. Paul Redfern, *Museveni Finally Gives in to GM Food Production*, Sept. 22, 2003, LEXIS, Global News Wire—Asia Africa Intelligence Wire file.

132. *Id.*

133. *Id.*

dry seasons."[134] In addition, "[f]armers in Brazil will soon plant genetically modified soybeans legally."[135] Such a move could potentially damage United States farmers because of Brazil's potential output of soy products,[136] but the move can still help the United States in its quest for easing the restrictions placed on GM Foods around the globe.

More nations appear to be lessening their grips on GM Foods. Based on the current regulatory systems in place in the EU and UN, and based on the more favorable treatment of GM Foods in nations around the world, the United States must be pleased, at least behind closed doors. Because GMOs are present in so many foods, from breakfast cereal to corn oils to frozen microwavable pizzas, the world will only see more headlines about the genetically modified food products in the coming months and years. It will be up to the hundreds of worldwide nations to work together to find a solution on how to properly test and regulate these crops, as their potential benefits far outweigh the short-term impacts and disadvantages. While it is clear how the United States will respond to world regulation of these foods, it is unclear how people around the globe will respond to GM Foods. Currently, the acceptance level for GM Foods is higher than in previous years, and much of the credit for this improvement should go to the progress made by international regulation and to the many compromises reached by nations around the globe.

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134. *Id.*

135. Reuters, *Brazilian Farmers About to Plant Legal GM Soy*, Sept. 25, 2003, *at* http://www.thecampaign.org/News/sept03g.php (last visited Sept. 30, 2003).

136. *Id.*